UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Clayton Myers

From: Kevin Sweeney, Senior Entomologist

Date: September 14, 2011

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 388174
Decision no.: 446100
Submission no: 891427
Action code: R310
Product Name: CMP119-003
EPA Reg. No or File Symbol: 8329-OE
Formulation Type: Oil based concentrate
Ingredients statement from the label with PC codes included: 5.0% pyrethrins (PC code 069001)
Application rate(s) of product: 0.0015 -0.008 lbs pyrethrins/acre per day
Use pattern: ULV mosquito adulticide

I. Action Requested: Review study and the new label for the subject product.

II. Background: This label only includes mosquitoes as pests. The registrant conducted a field study against two mosquito species (from the genera *Aedes* and *Culex*) to support the addition of mosquitoes and associated control claims to the label. Only mosquito control directions and claims are listed on the label.

III. MRID Summary: (see attached primary review)

1. The study does not fully comply with GLP and deficiencies are noted in the GLP statement. Raw data are printed out and reported in table form.
2.

a. The registrant conducted a field study with caged adult mosquitoes to assess the efficacy of the subject product. The study was conducted on three different days in 2010. The lowest undiluted rate evaluated in this study was slightly below the lowest label rate on the label (0.0015 lbs pyrethrins/acre). Testing with undiluted product was a more conservative approach to product efficacy when compared to the labeled 1:1 dilution in oil because the

latter dilution produces many more droplets for mosquito impingement.

b. Efficacy against two mosquito species (*Aedes aegypti* and *Culex quinquefasciatus*) was assessed in these field trials. None of the trials assessed the efficacy of the product against mosquitoes from the genus *Anopheles*. The adult mosquitoes tested in these trials were from laboratory colonies. Mosquitoes were 2-3 days old. They were not blood fed and were non-parous. A test unit consisted of a mosquito cage containing 20 individuals (mean was actually 18.6). Each test replicate consisted of were 9 cages of each in the treatment with species with one cage in untreated control. Three treated replicates of each species were placed in a row 50 feet apart with cages mounted on five feet stakes. Three rows were established downwind and perpendicular to the path of the spray truck at distances of 100, 200 and 300 feet. The untreated control was placed upwind of the application. Each application was made in accordance with the label and cages were removed from the field ten minutes later. Knockdown was and kill were evaluated at one and 24 hours post-treatment. Between the two days there were four replicates for each species (A, B, C. and D) at the 0.5 oz per acre rate. Additional *Ae. aegypti* replicates were tested with the 0.75 oz/acre rate.

c. Results were reported by replicate in the study and were pooled by the primary review. Reporting in both instances was in table form. The product treatment resulted in 90% kill (mean) of mosquitoes within 24 hours at an application rate of 0.5 oz/acre. The range was 87.2% to 96.2% for *Ae. aegypti* and 93.8% to 99.3% for *Cx. quinquefasciatus*. Knockdown was very good with more than 90% of the mosquitoes knocked-down in each row of cages within one hour post-treatment.

d. The study is acceptable.

IV. RECOMMENDATIONS:

1. Labeling
    a. Label claims and pests:
    The study is acceptable and supports mosquito claims and labeled uses against all mosquito genera except Anopheles.
    b. Directions for Use:
    The label should include instructions for preparing the 0.008 lbs a.i./acre rate for *Aedes taeniorhynchus* mosquitoes in the Application Rates tables. I also advise the risk manager to check to confirm the allowance for the high application rate following pyrethrins RED mitigation recommendations.

2. A study with Anopheline mosquitoes should be made a condition of registration and be due within 12 months of the date of registration.

3. The product includes directions for aerial spraying. An aerial spraying study should be conducted in at least two sites in the USA where mosquito populations are prevalent. Wild mosquito populations should be included in these trials. The product should be applied without a synergist as directed by the label. These data should be deemed as a

condition of registration and be due to the Agency in 18 months.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID: 484099-09; Krenick, F. CMP 119-003 Ground ULV Bioassay against Adult Female *Aedes aegypti* and *Culex quinquefasciatus* Mosquitoes, December 20, 2010.

Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments (810.3400)

Product Name: CMP 119-003
EPA Reg. No. or File Symbol: 8329-OE
Decision number: 446100
DP number: 388174

Prepared for
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-04

Primary Reviewer:
Robert Ross, M.S.

Signature: Robert H. Ross
Date: JUL 25 2011

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Date: JUL 25 2011

Quality Assurance:
Jennifer Goldberg, B.S.

Signature: Jennifer Goldberg
Date: JUL 25 2011

RECOMMENDED CLASSIFICATION: **Partially acceptable**

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE [810.3400]
MRID:	484099-09; Krenick, F. CMP 119-003 Ground ULV Bioassay against Adult Female *Aedes aegypti* and *Culex quinquefasciatus* Mosquitoes, December 20, 2010.
DP BARCODE:	388174
DECISION NO:	446100
SUBMISSION NO:	891427
SPONSOR:	Clarke Mosquito Control Products, Inc.; 110 East Irving Park Road, Roselle, Illinois 60172
TESTING FACILITY:	Clarke Technical Center, 1501 Wright Blvd., Schaumburg, Il 60193
STUDY DIRECTOR:	Fran Krenick, GLP System Manager,
SUBMITTER:	Karen Larsen, Director, Global Registrations, Clarke Mosquito Control Products, Inc.
STUDY COMPLETED:	20/12/2010
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	Conducted in compliance with GLP Standards, 40 CFR part 160, Federal Register Notice Vol. 54 No. 158; effective October 16, 1989 with the following exceptions: Quality Assurance was unable to perform an In-Life audit during the conduct of the study.

TEST MATERIAL:	PRODUCT NAME: CMP 119-003 EPA REGISTRATION NUMBER OR FILE SYMBOL: 8329-OE ACTIVE INGREDIENT NAME: Pyrethrins CHEMICAL NAME: Pyrethrins A.I. %: 5.18 PC CODE: 069001 CAS NO.: 8003-34-7 FORMULATION TYPE: Liquid applied as a ultra low volume non-thermal aerosol (cold fog). PRODUCT APPLICATION RATES: Undiluted up to 0.88 fl oz/acre/day (0.006 g/m^2/day; reviewer calculated); Undiluted up to 2.83 fl oz/acre/day (0.02 g/m^2/day; reviewer calculated) for *A. taeniorhynchus* or other difficult species. ACTIVE INGREDIENT APPLICATION RATE: Undiluted up to 0.0025 lbs/acre/day (0.00028 g/m^2/day; reviewer calculated); Undiluted up to 0.008 lbs/acre/day (0.0009 g/m^2/day; reviewer calculated) for *A. taeniorhynchus* or other difficult species.
PROPOSED LABEL MARKETING CLAIMS:	"Control of adult mosquitoes in Outdoor Residential, Recreational and other outdoor areas"
EPA REQUESTS:	[EPA WILL ADD DIRECTIVES HERE]

STUDY REVIEW

Study Number/Title: (if more than one study is provided in the MRID)

Purpose: To determine the efficacy of CMP119-003 against caged adult female *Aedes aegypti* and *Culex quinquefasciatus* mosquitoes.

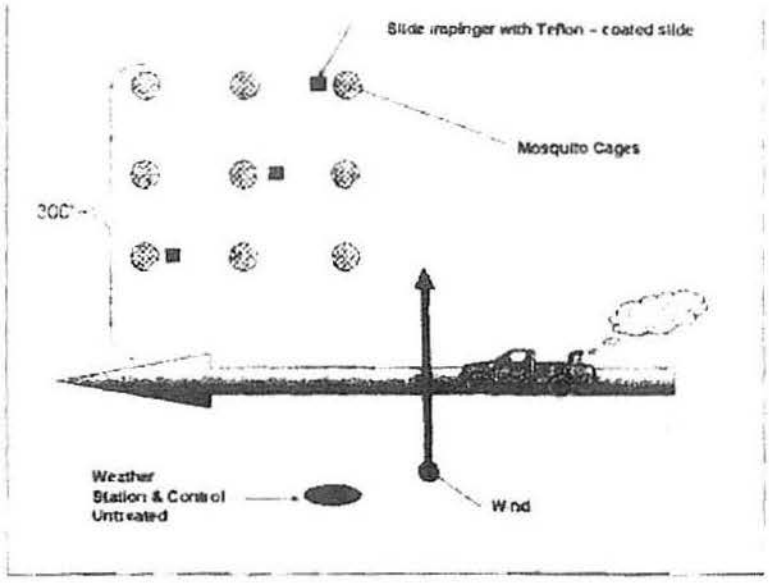
MATERIALS AND METHODS

Test Location : Open fields at the Lake Wales Municipal airport in Lake Wales, Florida between November 4, 2010 and November 9, 2010

Test Material(s): Liquid applied as a ultra low volume non-thermal aerosol (cold fog).
The reviewer does not know if the tested material is the same as the EPA product or file symbol. Application rates of 0.5 and 0.75 fl oz/acre which approximated two (0.53 and 0.74 fl oz/acre) of the label rates were used. These rates were below the highest recommended label rate.

Test Species Name, Life Stage, Sex and Age: Female adult mosquitoes *Aedes aegypti* and *Culex quinquefasciatus* were used. The mosquitoes were 2-3 days old and came directly from the Clark Technical Center Insectary and are presumed to be non egg bearing.

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: The experiments were conducted as caged open field trials in grassy fields within the Lake Wales, Florida airport. Cages containing one of the two mosquito species were placed on 5-foot high stakes and placed 100, 200, and 300 ft downwind of the truck (traveling at 10 mph) with the fogger at a 90° angle to the path the vehicle was traveling. Three cages were at each distance with a control cage upwind of the site (9 test cages and 1 control cage). See figure below.



List the treatments including untreated control: 0.5 oz/acre/day (0.003 g/m^2/day; reviewer calculated) for both species of mosquitoes and 0.75 oz/acre (0.0045 g/m^2/day; reviewer calculated) for *Aedes aegypti* and an untreated control for each test (presumed to be fl oz as indicated on label)

Number of replicates per treatment: Three replicates for each test. A fourth replicate (actually Replicate A) for the 0.50 oz./acre trial was performed but was not used in the summary tables because meteorological conditions prevented further trials until three days later.

Number of individuals per replicate: Ranged from 14.5 to 20.5 with an average of 18.6.

Length of exposure to treatment (time in seconds, minutes or hours): 10 minute exposures. Tested specimens were transferred to clean containers for knockdown and mortality monitoring.

Experimental conditions (state relative humidity, temperature, and photoperiod): Trials were conducted between 5:36 and 6:50 PM, with an average temperature of ~61° at 5 ft and wind speed of ~6 mph in 3 trials and ~2 mph in 3 trials. The humidity was ~57 %.

State data or endpoints that were to be collected/recorded: Number knocked down at 1 hour and number dead at 24 hours.

Were the data analyzed? If so, what statistical analyses were performed?

Yes. The mean knockdown at 1 hour and mean mortality at 24 hours were analyzed with respect to each of the three distance groups and with the control cage. LSD ($\alpha = 0.05$) $P<0.005$.

RESULTS

Raw data were included.

Protocol deviations were made as follows: "Modify section F2, second paragraph to read: Approximately 20-25 *Aedes aegypti* and approximately 15-20 *Culex quinquefasciatus* mosquitoes will be mouth aspirated into spray cages, fed a sugar water solution and placed in a sealed container or cooler and kept until placed in field for evaluation. Modify section F3 to read The ULV Sprayer will be calibrated to deliver CMP119-003 at 0.5 and 0.75 fluid oz. per acre....." The reviewer did not have access to the protocols to which these deviations apply.

As tables 1, 2 and 3 indicate, 1 hour knockdown and 24 hour mortality rates were good.

Table 1. *Aedes aegypi* summary data for CMP 119-003 at 0.5 oz/acre for each distance

Aedes aegypti	1 Hour Knockdown		24 Hour Mortality	
Distance	Mean Knockdown[1] (SE)	% Knockdown	Mean Mortality[1] (SE)	% Mortality
100 ft	60.0 (2.6) a	98.9%	58.3 (1.76)a	96.2%
200 ft	59.3 (0.67) a	98.3 %	56.0 (2.0)a	92.8%
300 ft	61.0 (1.0) a	97.3%	54.67 (0.88)a	87.2%
Untreated (Control)	0.0 (0.0) b	0.0%	0.0 (0.0) b	0.0%

[1] Means followed by the same letter are not significantly different $P<0.005$); mean separation by LSD ($\alpha = 0.05$), within each challenge set.

Table 2. *Culex quinquefasciatus* summary data for CMP 119-003 at 0.5 oz/acre for each distance

Culex quinquefasciatus	1 Hour Knockdown		24 Hour Mortality	
Distance	Mean Knockdown[1] (SE)	% Knockdown	Mean Mortality[1] (SE)	% Mortality
100 ft	46.67 (2.33) a	100%	46.33 (2.6) a	99.3%
200 ft	47.33 (4.26) a	98.6%	45.0 (3.8) a	93.8%
300 ft	42.67 (2.33) a	97.7%	41.0 (1.0) a	93.9%
Untreated (Control)	.067 (0.33) b	3.33%	.067 (0.33) b	3.33%

[1] Means followed by the same letter are not significantly different P<0.005); mean separation by LSD ($\alpha = 0.05$), within each challenge set.

Table 3. *Aedes aegypti* summary data for CMP 119-003 at 0.75 oz/acre for each distance

Aedes aegypti	1 Hour Knockdown		24 Hour Mortality	
Distance	Mean Knockdown[1] (SE)	% Knockdown	Mean Mortality[1] (SE)	% Mortality
100 ft	60.0 (1.0) a	98.4%	60.0 (1.15) a	98.4%
200 ft	53.67 (4.84) a	91.0%	52.67 (5.36) a	89.3%
300 ft	60.33 (1.67) a	96.8%	59.67 (2.33) a	95.7%
Untreated (Control)	0.0 (0.0) b	0.0%	0.0 (0.0) b	0.0%

[1] Means followed by the same letter are not significantly different P<0.005); mean separation by LSD ($\alpha = 0.05$), within each challenge set.

Since control mortality was not greater than 5 %, correction by Abbott's Formula was not necessary.

The mean knockdown at 1 hour and mean mortality at 24 hours were analyzed with respect to each of the three distance groups and with the control cage. The level of significance reported was $P<0.005$. Data were expressed as mean (SE). A median value was not calculated.

Study Authors Conclusions

The overall mortality at 0.5 oz./acre was 93.9% for both species and at 0.75 oz./acre was 94.5% for *Aedes aegypti*. There were no statistical differences between distances. The authors noted that if one cage at the 200 ft. distance in the 0.75 oz./acre trial, which did not receive the desired spray, was removed from consideration, the overall mortality would be 96.7%.

Reviewers Conclusions

Abbott's Formula was not necessary because of the low mortality in controls. The reviewer agrees with the study authors that both formulations tested were efficacious for overall mortality for both *Aedes aegypti* and *Culex quinquefasciatus* mosquitoes.

Reviewer Recommendations

This study is only partially acceptable because it only tested two species of mosquitoes (*Aedes aegypti* and *Culex quinquefasciatus*) and the label states that CMP119-003 "may be used to control adult mosquitoes" (implying all species of mosquitoes), "flies, and gnats...." Additional data would be required to fully support the label claim.